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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,210	03/27/2001	Peter Wagner	20144-000910	3853

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/820,210

Applicant(s)

WAGNER ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I.** Claims 1-13, 24, 26, 27, 29, 31, and 34, drawn to heterofunctional crosslinking reagents and conjugates containing them, classified based on the final structure of the reagents and conjugates.
- II.** Claims 14-23, 25, 28, 30, and 32, drawn to heterocrosslinking compounds and conjugates containing them, classified based on the final structure of the reagents and conjugates.
- III. Claims 33 and 35-44, drawn to protein arrays, classified in class 436.
- IV.** Claims 45, drawn to a method of attaching a protein to a solid support, classified in class 530.
- V.** Claims 46, drawn to a method of covalently attaching a protein to a crosslinking reagent.
- VI.** Claims 47-52, drawn to a method of attaching a crosslinker to a recombinant protein., classified based on the structure of the final product.
- VII.** Claims 53-58, drawn to a method of attaching a crosslinker to a recombinant protein.
- VIII.** Claims 59-64, drawn to a method of attaching a crosslinker to a recombinant protein.
- IX. Claims 65-67, drawn to a method of attaching an altering member to a polypeptide.
- X.** Claims 68-72, drawn to a method of covalently linking a protein to a compound.
- XI.** Claims 73-77, drawn to a heterofunctional crosslinker, classified based on the chemical structure of the crosslinker.

**** Each of these groups is inclusive of numerous patentably distinct inventions. A distinct invention is defined, for example, by the combination of a specific species to define each of L^1 - L^3 and W in Invention I and a combination of specific species to define each of L , L^1 and L^2 for Invention II. If either Invention I or Invention II is elected, applicants must further elect a single combination of the noted variables which will define the elected invention. For Inventions IV-VII a species of "heterofunctional crosslinking reagent"**

must be elected; for Inventions VIII and X, the election of a "heterofunctional crosslinking reagent" species must include an election of a specific species as defined in each of (a), (b), (c), and (d); for Invention XI, an election must be made of a species as defined in each of i)-iv). . An examination on the merits will be conducted for the specific elected invention as defined by the elected variables and all other species which are patentably indistinct from the elected invention.

2) The inventions are distinct, each from the other because of the following reasons:

Inventions I-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve chemically diverse products and reactants for producing them. For example:

(i) The core structure $L^1-W(L^3)-L^2-$ of Invention I which contains three linking groups is different in structure and function from the core structure $-L^1-L-L^2-$ of Invention II.

(ii) The "protein array" of Invention III requires none of the chemical structures required by any of the other inventions.

(iii) The "heterofunctional linker" of Invention XI does not require the structural features of any of the other inventions.

(iv) The methods of preparation of each of Inventions V-X require different types of reactants and reaction conditions and produce different types of products.

3) Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as evidenced by diverse classification requiring a burdensome search, restriction for examination purposes as indicated is proper. It is additionally noted that very different patentability considerations are involved for each of the

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inventions. For example, a patentability determination for Invention I would require a determination of the novelty and unobviousness of a specific compound while a patentability determination for Invention III would require a determination of the novelty and unobviousness of the combination of a layered array comprised of a substrate, a thin film and immobilized protein patches. Clearly both the search required and the nature of the patentability determination for each of these inventions is very different in nature.

4) Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5) Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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August 15, 2002

Mary E. Ceperley
Mary E. (Molly) Ceperley
Primary Examiner
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